Examiner also argues that "Falk teaches a similar device having two temperature sensors, the first 220 for measuring the temperature of target tissue and the second 210 for measuring the temperature of the fluid in a lumen of the device." The Examiner concludes it would have been obvious to include the two temperature sensors taught by Falk in the device of Stenberg.

Applicants respectfully disagree and submit that the Examiner has not provided the requisite motivation to combine these references. Indeed, the only attempt by the Examiner to demonstrate a motivation to combine the references is the Examiner's statement on page 2 of the Office Action that "it would have been obvious to one of ordinary skill in the art . . . to include two temperature sensors as in Falk, one in the lumen measuring the fluid temperature and one to measure the tissue temperature, in the device of Stenberg in order to ensure safe and effective use of the device." This statement falls short of evidencing any motivation to combine references because while there is always a desire to develop a safe and effective device, the manner of doing so is not always clear.

The Examiner fails to apply the legal requirement that the prior art be shown to provide sufficient motivation to one of ordinary skill in the art to combine the references. Thus, in combining references in an obviousness rejection, an examiner may not simply pick and choose elements from different references, but must identify a teaching or motivation to combine the elements. The Federal Circuit has stated:

> Our case law makes clear that the best defense against the subtle but powerful attraction of a hindsight-based obviousness analysis is rigorous application of the requirement for a showing of the teaching or motivation to combine prior art references. *See, e.g., C.R. Bard, Inc. v. M3 Sys., Inc.*, 157 F.3d 1340, 1352, 48 USPQ2d 1225, 1232 (Fed. Cir. 1998) (describing "teaching or suggestion or motivation [to combine]" as an "essential evidentiary component of an obviousness holding"); *In re Rouffet*, 149 F.3d 1350, 1359, 47 USPQ2d 1453, 1459 (Fed. Cir. 1998) ("the Board must identify specifically . . . the reasons one of ordinary skill in the art would have been motivated to select the references and combine them"); *In re Fritch*, 972 F.2d 1260, 1265, 23 USPQ2d 1780, 1783 (Fed. Cir. 1992) (examiner can satisfy burden of obviousness in light of combination "only by showing some objective teaching [leading to the combination]"); *In re Fine*, 837 F.2d 1071, 1075, 5 USPQ2d 1596, 1600 (Fed. Cir. 1988) (evidence of teaching or suggestion "essential" to avoid

> hindsight); *Ashland Oil, Inc. v. Delta Resins & Refractories, Inc.*, 776 F.2d 281, 297, 227 USPQ 657, 667 (Fed. Cir. 1985) (district court's conclusion of obviousness was error when it "did not elucidate any factual teachings, suggestions or incentives from this prior art that showed the propriety of combination"). *See also Graham*, 383 U.S. at 18, 148 USPQ at 467 ("strict observance" of factual predicates to obviousness conclusion required). Combining prior art references without evidence of such a suggestion, teaching, or motivation simply takes the inventor's disclosure as a blueprint for piecing together the prior art to defeat patentability--the essence of hindsight. *See, e.g., Interconnect Planning Corp. v. Feil*, 774 F.2d 1132, 1138, 227 USPQ 543, 547 (Fed. Cir. 1985) ("The invention must be viewed not with the blueprint drawn by the inventor, but in the state of the art that existed at the time.").

In re Dembiczak, 50 USPQ2d 1614 (Fed. Cir. April 28, 1999).

The Examiner has not provided clear and particular reasons for incorporating into the device of Stenberg one or more temperature sensors. Rather, he simply concludes that a requisite motivation exists "in order to ensure safe and effective use of the device." This type of conclusory statement falls well short of the requirement to specifically identify the reasons why one of ordinary skill in the art would be motivated to combine the references. In fact, there is no valid argument that sufficient motivation exists to modify Stenberg to include one or more temperature sensors.

Stenberg and Falk are directed to subject matter that is entirely different. Stenberg is a rather crude system for cooling a live systemic organ. The system relies on passive cooling by circulating ice water through the tubing system that is in contact with the organ to be cooled. The use of a temperature sensor in such a system would be useless because there is no way to regulate the temperature of the ice bath or the organ. The Stenberg system can essentially be regarded as a type of qualitative cooling system in which cooling takes place by virtue of circulating ice water, and the extent of cooling need not be measured. "[T]he mere fact that the prior art may be modified in the manner suggested by the Examiner does not make the modification obvious unless the prior art suggests the desirability of the modification." *In re Fritch*, 23 USPQ 2d 1780, 1783-84 (Fed. Cir. 1992). The Examiner has failed to point to any suggestion or motivation in either reference to make such a modification.

The Falk reference certainly provides no such modification as it, unlike Stenberg, is intended to *raise* the local temperature of tissue exposed during surgery. In a further departure from Stenberg, Falk does not use any sort of fluid recirculation system which places a heat conductive element in *direct contact* with the target body organ. Instead, *hot air* is blown into the tissue exposed by the surgical incision. The teachings of Falk could not be applied to brain tissue (an important application of Applicants' invention) as heat worsens brain injury causing further injury. Further, the delivery of hot air, as disclosed by Falk, can be detrimental to many organ and tissue systems, including the brain, because it can result in excessive drying.

The danger of overheating an organ or burning tissue, combined with the ability to regulate air flow and temperature, may have motivated Falk to use a temperature sensor in his system. But, the use of a temperature sensor in the Falk reference does not provide any type of suggestion or motivation to so modify a crude cooling system such as that disclosed by Stenberg. After all, the cooling system disclosed by Stenberg is so crude that it cannot expected to be so efficient that there exists any risk of overly cooling the tissue (i.e., a kidney). Thus, there would be no point in combining Falk's hot-air, temperature monitored system, with Stenberg's passive ice bath system.

The Examiner is clearly using the claimed invention as a template to piece together the teachings of the prior art so that the claimed invention is rendered obvious. And, the Federal Circuit has warned that "[o]ne cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to duplicate the claimed invention." *In re Fine*, 5 USPQ 2d 1596, 1600 (Fed. Cir. 1988).

For these reasons Applicants submit that the Falk and Stenberg references cannot be combined and that the rejection of claims 1-5, 7, 8, 12, 19, 46, and 49 should be withdrawn.

Applicants further note that the rejection of the claim 19 is improper because neither Stenberg nor Falk disclose or suggest an apparatus of the type set forth in claim 1, much less such an apparatus in which the implantable member is constructed of a shape memory material. The Examiner argues that because the Stenberg device is made from a "formable metal wire" that the reference discloses a shape memory material. This is incorrect. A metal wire or, or any other material that can be formed to a desired shape is not a "shape memory material." A shape

memory material is known by one having ordinary skill in the art to be a material that can be deformed from an at-rest shape to a first shape upon an application of a force, and which will return to the at-rest shape upon removal of the force. Although a formable metal wire type disclosed in Stenberg can be formed into a desired shape by the application of a force, such as a manual force, once the force is removed, the formable wire does not return to its original shape. Rather, it can only return to the original shape by the application of another force. This is a further reason why the rejection of claim 19 should be withdrawn.

Regarding the rejection of claim 46, the Examiner admits that the combination of Stenberg and Falk fails to teach the first temperature sensor being positioned on a tissue-contacting portion of the implantable member. The Examiner argues, however, that it would have been obvious to place the first temperature sensor on a tissue-contacting surface of the device in order to effectively measure the treated tissue directly adjacent treatment device.

Applicants respectfully disagree and submit that in addition to the reasons noted above why the rejection of claim 46 is improper, there can be no possible motivation to place the temperature sensor on a tissue-contacting surface of the device because no portion of the Stenberg device is in contact with tissue. Instead, Stenberg's device merely blows hot air onto a surgical incision. Further, there would be no point in placing a temperature sensor on a tissue-contacting surface of the Stenberg device because, as noted above, there is no ability to regulate the temperature in a system such as that disclosed by Stenberg, and thus there would be no need or desire to place a temperature sensor on the cooling device itself.

Claim 49 is an independent claim that likewise distinguishes over the combination of Stenberg and Falk. Claim 49 is directed to an apparatus for thermally affecting tissue, comprising: (1) an implantable member having an outer surface configurable to contact target tissue; (2) at least one fluid-tight lumen defined by the implantable member, the fluid-tight lumen being in thermal communication with the outer surface of the implantable member and being configured to receive a thermally transmissive fluid to thereby impart a temperature-reducing thermal change to the outer surface of the implantable member; and (3) a temperature sensing element disposed within the lumen that is effective to measure the temperature of any fluid within the lumen.

Falk fails to disclose or suggest any sort of system or device that includes a fluid-tight lumen in thermal communication with the outer surface of an implantable member, and which is configured to receive a thermally transmissive fluid. Falk further fails to disclose or suggest such a device or system in which the thermally transmissive fluid is effective to impart a temperature-reducing thermal change to the outer surface of the implantable member, and a temperature sensor disposed within the fluid-tight lumen that is effective to measure the temperature of any fluid within the lumen. For these reasons, the combination of Stenberg and Falk, assuming that it is legally proper to combine such references, still does not disclose or suggest all of the elements of claim 49. Despite Falk using a temperature sensor to detect tissue temperature, it still does not disclose or suggest placing a temperature sensor in a fluid-conveying lumen to measure the temperature of a coolant therein.

For these reasons, the rejection of claims 1-5, 7, 8, 12, 19, 46, and 49 is improper and should be withdrawn.

Claims 6, 9-11, and 47

The Examiner rejects claims 6, 9-11, and 47 as being obvious over Stenberg and Falk as applied to claims 1 and 5 and further in view of U.S. Patent No. 5,609,620 (Daily). Applicants respectfully disagree and for the reasons noted below request that this rejection be withdrawn.

Regarding the rejection of claim 6, the Examiner relies upon Daily to disclose an apparatus that may be formed from a silicone elastomer. Applicants note that for the reasons discussed above, Stenberg and Falk cannot be properly combined to render obvious claim 1 (from which claim 6 ultimately depends) and the Daily reference, alone or in combination with either of Stenberg or Falk, does not disclose or suggest the subject matter of claim 6.

With respect to the rejection of claims 9 - 11, Applicants again note that Stenberg and Falk cannot be properly combined to reject claim 1 and that Daily, alone or in combination with either Stenberg or Falk, fails to disclose or suggest the elements of dependent claims 9-11.

The Examiner also rejects claim 47 as being obvious over Stenberg and Falk in view of Daily alleging that this combination of references teaches all limitations of the claim except for the first temperature sensor being positioned on the backing member. The Examiner argues that

it would have been obvious to one of ordinary skill in the art to place the temperature sensor on the backing member of the device in order to effectively measure the treated tissue directly adjacent the treatment device.

Once again, the Examiner uses hindsight to reconstruct the claimed invention. There is no mention whatsoever of any temperature sensor for the system disclosed by Stenberg. In fact, Applicants note above why such a temperature sensor would be pointless. Falk's system is very different that Stenberg's, as well as the claimed invention, because it simply directs hot air into a surgical incision to warm tissue locally. Flak's system does not directly contact tissue, and it would probably present unwanted dangers if it was configured to contact tissue. Thus, the combination of references proposed by the Examiner plainly does not teach the claimed invention in which a temperature sensor is positioned on a thermally-transmissive, non-adhering backing member.

For these reasons, the rejection of claims 6, 9 – 11, and 47 should be withdrawn.

Claims 15, 17, and 18

The Examiner rejects claims 15, 17, and 18 as being obvious over Stenberg in view of Falk as applied to claim 1 and further in view of U.S. Patent No. 5,891,134 (Goble). In support of this rejection, the Examiner argues that Stenberg and Falk teach all limitations of these claims except for the pressure measurement element. The Examiner argues that Goble teaches "an apparatus for thermally affecting tissue including a pressure sensor 58 and pressure warning alarm 62 in order to ensure that fluid pressure in the device does not adversely affect the device and surrounding tissue. It would have been obvious to one of ordinary skill in the art at the time of the invention to include a pressure measurement element as in Goble et al. between the implantable member and the tissue in the device of Stenberg and Falk to ensure that the pressure exerted by the device does not harm surrounding tissue." Applicants respectfully disagree and submit that the Examiner impermissibly combines these references and applies hindsight to justify this rejection.

As noted above, Stenberg and Falk cannot be combined because there is no proper motivation to do so. In any event, and as the Examiner acknowledges, Stenberg and Falk alone

or in combination with each other fail to disclose any sort of pressure measurement element. While Goble may disclose a pressure measurement element, it is only a device that measures the pressure of fluid within an inflatable balloon to ensure that the balloon does not burst while treating a patient. Goble fails to disclose or suggest any sort of pressure measurement device of the type claimed which is effective to measure the pressure at which a surgical device is applied to target tissue during a treatment regimen. This is exceedingly important in devices implanted below the skull because the skull cannot expand and pressure is instead transmitted to the brain with ensuing brain tissue injury.

Goble is quite different than the claimed invention because it is directed to a device and system that applies *thermal* energy to tissue to ablate uterine tissue such as for the purposes of endometrial ablation. The Goble device has a distendible bladder which has an electrode assembly positioned therein. The bladder is filled with a conductive fluid such as saline. In use, the bladder is inflated by the addition of the fluid and the electrodes are activated to heat the fluid within the vessel and to heat the bladder in order to ablate the uterine tissue that it contacts. With a device such as that disclosed by Goble, firm contact must be maintained between the distendible bladder and the uterine tissue in order to effect ablation. Moreover, there is no danger that undue pressure would harm the underlying tissue. Although the Examiner states that it would have been obvious to include the pressure measurement device of Goble "between the implantable member and the tissue and the device of Stenberg and Falk to ensure that the pressure exerted by the device does not harm surrounding tissue" there is no such teaching or suggestion in Goble or any of the other references. In fact, Goble never suggests harm to tissue as a result of excess pressure. That phenomenon is completely fabricated by the Examiner. Only the pressure of fluid with the Goble balloon is of concern to Goble, and only because excess fluid pressure could cause the balloon to burst, leading to potentially serious health consequences for the patient.

For the forgoing reasons, Applicants respectfully submit that the Examiner's rejection of claim 15 is improper. Claims 17 and 18 depend from claim 15 and thus contain all limitations thereof. Thus, the rejection of these claims is improper and should be withdrawn as well.

Claim 48

Claim 48 is rejected as being obvious over Stenberg in view of U.S. Patent No. 5,108,407 (Geremia). In support of this rejection, the Examiner argues that Stenberg teaches all limitations of claim 48 except for the shape memory material being deformed under force and returning to an at-rest shape after removal of the force. The Examiner relies upon the Geremia reference to disclose a shape memory material, arguing that it would have been obvious to one of ordinary skill in the art at the time of the invention to make the coil of Stenberg out of a shape memory material as described in Geremia to ensure that the implantable device better conforms to the area of tissue that will be treated by the device. Applicants respectfully disagree and submit that the Examiner's rejection is legally improper. Once again, the Examiner attempts to combine entirely disparate references relying upon conclusory, unsupportable statements in an attempt to demonstrate motivation to combine the references.

In support of this rejection, the stated motivation is "to ensure that the implantable device better conforms to the area of tissue that will be treated by the device." This does not constitute any acceptable rationale for combining Geremia with Stenberg because the Stenberg device, which utilizes a formable or malleable wire, can already be conformed to any desired shape in order to conform to treated tissue. There is no suggestion or motivation in any prior art reference that a *shape memory material* could be useful to better conform to the area of tissue that will be treated by the device. A shape memory material is utilized in the Geremia reference, which is prior art that is entirely non-analogous to the claimed invention and to Stenberg. The Geremia device must utilize a shape memory material to permit intravascular delivery and subsequent treatment using the device. That is, the embolic coil of Geremia must be inserted through a catheter that is disposed in a blood vessel. A coil-shaped device, which is the preferred treatment configuration of the Geremia device, obviously cannot be inserted through a blood vessel. Thus, the device is inserted through a catheter in order to be configured as an elongate object. In the delivery mode, the walls of the catheter provide a force that cause the device to change from a coiled to a linear object. Once the device emerges from the catheter (i.e., when the shape-changing force is removed), it returns to its coiled shape. There is no suggestion in either Geremia or Stenberg that a shape memory material could be useful in the design of a device that is used to cool body organs.

suggestion in either Geremia or Stenberg that a shape memory material could be useful in the design of a device that is used to cool body organs.

For the forgoing reasons, Applicants submit that the Examiner's rejection is legally improper and must be withdrawn.

In view of the forgoing remarks, Applicants submit that all pending claims are in condition for allowance and Applicants respectfully requests allowance thereof. The Examiner is urged to telephone the undersigned attorney for Applicants in the event that such communication is deemed to expedite allowance of this application.

Dated: September 23, 2003

Respectfully submitted,

By _____

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